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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,608	03/24/2004	Bahram Ghaffarzadeh Kermani	01-00011	7232
29389	7590	03/10/2005	EXAMINER	
ILLUMINA, INC. 9885 TOWNE CENTRE DRIVE SAN DIEGO, CA 92121-1975			ZHOU, SHUBO	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 03/10/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/809,608

Applicant(s)

KERMANI, BAHRAM
GHAFFARZADEH

Examiner

Shubo (Joe) Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 30-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29, 47 and 48 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 12 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/31/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Amendments

Applicants' election, without traverse, of Group I (claims 1-29, and 47-48) in the communication filed 10/26/04, is acknowledged.

Claims 1-48 are currently pending, and claims 1-29, and 47-48 are under examination.

Claims 30-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Information Disclosure Statement

The Information Disclosure Statement filed 8/31/04 has been entered and considered. Initialed copies of the form PTO-1449 are enclosed with this action.

Specification

The specification is objected to because of the following:

It appears that trademark is used in this application, such as INTEL on page 9. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The specification is objected to also because the Brief Description of the Drawings at page 4 fails to correspond to the actual drawing. The specification refers to Figure 10, but the Drawings filed 7/12/04 do not have Figure 10, but Figure 10A, Figure 10B, Figure 10C, and Figure 10D.

Appropriate correction is required.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-29, 47, and 48 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step in claims 1, and 47, and their dependent claims, is determining set points after identifying the control points and before determining parameters of a registration transformation equation. See Figure 4, and page 21 of the specification, wherein it is clearly stated:

“After the control points are identified in step 220, set points can be determined in step 222. In this step, a set of set points is defined for the control point sets such that each set point is the location on a sweep reference line or curve where a control point is transferred. Typically, set points are approximately equally-spaced values on the sweep

reference line or curve, for example, points on the axes between the fixed values of 0 and 2 such that the mean would fall on 1. ...

Once the location of the set points has been determined in step 222, the parameters of a registration transformation equation can be determined according to the change in location occurring for the control points that are projected to the set points in step 224. ...”

Thus, without having the set points determined, i.e. points on the sweep line to which control points are to be transferred, the step of determining parameters of a registration transformation equation cannot be executed.

Further, a step of determining set points would be a link between step (b) of claim 1, i.e. identifying sweep points, and the other steps, which link is missing in claim 1, as currently written.

The limitation of “wherein said signal transformation is selected from the group consisting of natural logarithm, base 2 logarithm” in claim 29 is lacks clear antecedent basis. In claim 1, the signals are transformed by a registration transformation equation, but the limitation in claim 29 does not provide a clear and concise equation although it may imply one.

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 19, and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hill et al. (Genome Biology, Vol. 2, No. 12, pages 1-13, 2001).

Hill et al. disclose different methods of normalizing microarray data including constant mean normalization and frequency normalization. The microarray data comprise expression data for genes from oocytes or two-week old worms. See page 10, right column, last paragraph. Since Hill et al. do not point out these oocytes or two-week old worms are not diploid, it would be readily recognized by one of ordinary skill in the art that the two-week old worms would be diploid. Therefore, the genome of the worms used for the experiment comprises two alleles of every locus. Further, the array (such as the A array on referred to on page 10) comprises sets of probes, and each set consists of 20 distinct probe pairs designed to monitor one single transcript. Thus, the 20 different probes are designed to detect different alleles of a single locus. See page 10, right column. Since the microarray is performed using total RNA as target nucleic acids isolated from the worms, it would be recognized by one of skill in the art that the expression data would comprise the different signals of the different alleles of any locus (see also page 11, lines 1-2. The expression data are presented in a Cartesian coordinate system. See Figures 1 and 2. This reads on the limitations of step (a) of claim 1. Hill et al. disclose a normalization method referred to as frequency normalization. Hill et al. state (see page 4, left column, last paragraph, and the right column, Figure 2):

“The specific hybridization intensity (AD) value for each of the 11 spike-in controls is plotted as a function of transcripts frequency in units of transcripts per million. The

points are fitted with a generalized linear model that is then used as a calibration curve to compute frequencies from the AD values of the other genes on the array."

Those points that are on the solid fitted line in Figure 2 are interpreted to read on the sweep points as recited in step (b) of claim 1 because sweep points are defined as "a set of points that are spaced according to a defined function along a line or curve" (page 7 of the specification). Those points that are not on the fitted line but close to the line are interpreted to read on the control points as recited in step (c) of claim 1 because they are for calibration and normalization as a control point is defined as "a signal value upon which normalization is based." See also page 7 of the specification.

Hill et al. disclose that using the fitting curve, chip sensitive as a parameter is determined as shown by the vertical line in Figure 2. All the other signal values of other genes on the array are calibrated and thus transformed based on the curve. These reads on steps (d) and (e).

As to claim 2-5, Hill et al. disclose some of the genetic data in a graphical format such as those in Figures 1, 2, which are Cartesian coordinates, and some in tabular format such as those in Tables 1-2. The probe sets on the arrays used by Hill et al. comprise thousands of genes. See page 10, right column.

As to claims 6-8, Hill et al. disclose that a mild curvature is noticed when a power law model is fitted to the data in Figure 2 indicating that there is a saturation, and use of 1 microgram cRNA would eliminate the saturation. This reads on the limitation of "upper limit" of claim 7. Figure 2 also shows the cutoff line for the limit of detection (the vertical line). This reads on the limitation of "lower limit" in claim 8.

As to claim 19, as set forth above, the sweep points are located on a line in Figure 2.

As to claim 22, the coordinate system disclosed by Hill et al. in Figure 2 comprises two dimensions, i.e. the axes X and Y.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 5 depends from claim 1 and the only extra limitation therein is that “n is at least 2.” However, claim 1 already requires that “n is an integer greater than one.” An integer that is greater than one is at least 2.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

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the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.



Patent Examiner

Ardi J. Mansel 3/7/05
ARDI J. MANSSEL
PATENT EXAMINER